

**IN THE CLAIMS:**

Please amend the claims as follows:

1. **(Currently Amended)** A dispersible [[and]] or orodispersible solid pharmaceutical composition having the form of particles with a size lower than 710  $\mu\text{m}$ , containing [[the]] a metformin active ingredient, ~~characterized in that it comprises wherein the particles comprise:~~
  - a) from 65% to 90% [[in]] by weight of the metformin active ingredient, optionally under provided in the form of a salt, or a combination of the metformin active ingredient with a hypoglycemic active ingredient;
  - b) from 0.5 to 4% [[in]] by weight of a binding agent or a combination of binding agents;
  - c) from 1% to 12% [[in]] by weight of a disintegrating agent or a combination of disintegrating agents;
  - d) from 0% to 10% [[in]] by weight of a diluting agent or a combination of diluting agents;
  - e) from 0.05% to 3% [[in]] by weight of a sweetening agent or a combination of sweetening agents; and
  - f) one or more additional excipients,the weight percentages being expressed based on the total weight of said composition.

2. **(Currently Amended)** A composition according to claim 1, characterized in that it also comprises further comprising from 0.01% to 6% [[in]] by weight of a flavouring agent, or a combination of flavouring agents.

3. **(Currently Amended)** A composition according to claim 1, characterized in that wherein the binding agent(s) is (are) are selected amongst from the group consisting of polyvinylpyrrolidone, sodium carboxymethylcellulose, alginic acid, hydroxypropylmethylcellulose and polyethylene oxide.

4. **(Currently Amended)** A composition according to claim 1, characterized in that wherein the disintegrating agent(s) is (are) are selected amongst from the group consisting of sodium croscarmellose, cross-linked polyvinylpyrrolidone, sodium starch glycolate, wheat or corn starch and pre-gelatinized starch.

5. **(Currently Amended)** A composition according to claim 1, characterized in that wherein the diluting agent(s) is (are) are selected amongst from the group consisting of lactose, mannitol, cellulose, microcrystalline cellulose and calcium carbonate.

6. **(Currently Amended)** A composition according to claim 1, characterized in that wherein the sweetening agent(s) is (are) are selected amongst

from the group consisting of gluconate, aspartame, cyclamate, sodium saccharinate, xylitol and maltitol.

7. **(Currently Amended)** A composition according to claim 2, characterized in that wherein the flavouring agent(s) ~~is (are)~~ are selected amongst from the group consisting of fruit flavour, mint flavour, anise flavour, honey flavour, vanilla flavour, tea flavour, and verbena flavour.

8. **(Currently Amended)** A composition according to claim 1, characterized in that wherein the metformin active ingredient [[has]] is provided in the form of a salt selected amongst from the group consisting of the phosphate, sulfate, hydrochloride, salicylate, maleate, benzoate, ethanedisulfonate, fumarate, succinate, chlorophenoxyacetate, embonate and glycolate salts.

9. **(Currently Amended)** A composition according to claim 1, characterized in that wherein the hypoglycemic active ingredient, when present, is selected amongst from the group consisting of glicazide, glipizide, chlorpropamid, glimepiride, glibenclamide, and derivatives combinations thereof.

10. **(Currently Amended)** A composition according to claim 1 characterized in that it comprises, additionally, further comprising a PPAR Gamma agonist (peroxisome proliferator-activated receptor gamma) or Glitazone, selected

amongst from the group consisting of rosiglitazone, pioglitazone, and balaglitazone and derivatives combinations thereof.

11. **(Currently Amended)** A composition according to claim 1 characterized in that it comprises, additionally, further comprising a PPAR Gamma and Alpha agonist or Glitazar selected amongst from the group consisting of terapglitazar, muraglitazar, and ragaglitazar and derivatives combinations thereof.

12. **(Currently Amended)** A composition according to claim 1 characterized in that it comprises, additionally, further comprising a fibrate-type hypocholesterol agent of fibrate type, such as fenobibrate and derivatives thereof.

13. **(Currently Amended)** A composition according to claim 1 characterized in that it comprises, additionally, an active ingredient selected amongst further comprising a dipeptidyl peptidase inhibitor (DPPIV).

14. **(Currently Amended)** A composition according to claim 1 characterized in that it comprises, additionally, further comprising acarbose or derivative thereof.

15. **(Currently Amended)** A composition according to claim 1, characterized in that it comprises comprising:

a) from 65% to 80% [[in]] by weight of the metformin active ingredient, optionally under provided in the form of a salt, or a combination of the metformin active ingredient with a hypoglycemic active ingredient;

b) from 0.5 to 4% [[in]] by weight of a water-soluble polyvinylpyrrolidone with a molecular ranging from 44,000 to 54,000;

c) from 1% to 10% [[in]] by weight of a water-insoluble cross-linked polyvinylpyrrolidone;

d) from 0.5% to 10% [[in]] by weight of a diluting agent or a combination of diluting agents;

e) from 0.05% to 3% [[in]] by weight of a sweetening agent or a combination of sweetening agents; and

f) one or more additional excipients,

the weight percentages being expressed based on the total weight of said composition.

16. **(Currently Amended)** A composition according to claim 1, characterized in that it comprises wherein the particles comprise (i) an internal core comprising the active ingredient or the combination of active ingredients, in association with one or more excipients and (ii) an external layer comprising the sweetening agent.

17. **(Currently Amended)** A composition according to claim 16, characterized in that wherein the internal core accounts for 75% to 85% [[in]] by

weight and in that the external layer accounts for 15% to 25% [[in]] by weight, based on the total weight of the composition.

18. **(Currently Amended)** A composition according to any one of claims 16 or 17, wherein:

(i) the internal core comprising comprises:

a) from 65% to 80% [[in]] by weight of the metformin active ingredient, optionally under provided in the form of a salt or a combination of the metformin active ingredient with a hypoglycemic active ingredient, and

b) from 0.5% to 4% [[in]] by weight of a binding agent or a combination of binding agents;

and

(ii) the external layer is non-film coated and comprises:

a) from 0% to 10% [[in]] by weight of a diluting agent or a combination of diluting agents;

b) from 1% to 10% [[in]] by weight of a disintegrating agent or a combination of disintegrating agents; and

c) from 0.05% to 3% [[in]] by weight of a sweetening agent or a combination of sweetening agents;

the weight percentages being expressed based on the total weight of said composition.

19. **(Currently Amended)** A composition according to claim 18, characterized in that wherein the binding agent is a water-soluble polyvinylpyrrolidone with a molecular weight ranging from 44,000 to 54,000.

20. **(Currently Amended)** A composition according to claim 18, characterized in that wherein the disintegrating agent is a water-insoluble cross-linked polyvinylpyrrolidone.

21. **(Currently Amended)** A composition according to claim 18, wherein:

(i) the internal core comprises:

a) from 76% to 77% [[in]] by weight of the metformin active ingredient, optionally under provided in the form of a salt or a combination of the metformin active ingredient with a hypoglycemic active ingredient, and

b) from 2.5% to 3.5% [[in]] by weight of a water-soluble polyvinylpyrrolidone with a molecular weight ranging from 44,000 to 54,000;

and

(ii) the external non film-coated layer comprises:

a) from 6.5% to 7.5% [[in]] by weight of a diluting agent or a combination of diluting agents;

b) from 4.5% to 5.5% [[in]] by weight of a water-insoluble cross-linked polyvinylpyrrolidone; and

c) from 0.5% to 2.5% [[in]] by weight of a sweetening agent or a combination of sweetening agents;

the weight percentages being expressed based on the total weight of said composition.

22. **(Currently Amended)** A composition according to claim 1, characterized in that it consists in wherein the particles comprise:

- (i) an internal core comprising:
  - a) ~~76,92%~~ in 76.92% by weight of the metformin hydrochloride active ingredient, and
  - b) 3.08% [[in]] by weight of a water-soluble polyvinylpyrrolidone with a molecular weight ranging from 44,000 to 54,000;
- and
- (ii) an external non film-coated layer comprising:
  - a) 7% [[in]] by weight of a diluting agent or of a combination of diluting agents;
  - b) 5% [[in]] by weight of a water-insoluble cross-linked polyvinylpyrrolidone;
  - c) 2% [[in]] by weight of a sweetening agent or a combination of sweetening agents;
  - d) 5% [[in]] by weight of a flavouring agent or a combination of flavouring agents; and
  - e) 1% [[in]] by weight of a preservative;

the weight percentages being expressed based on the total weight of said composition.

23. **(Currently Amended)** A hydrodispersible non film-coated pharmaceutical tablet, characterized in that it consists in comprising a composition according to claim 1.

24. **(Currently Amended)** A tablet according to claim 23, which wherein a pharmacokinetic profile is established from two tablets, each dosed at 500 mg, which is characterized by an area under the plasma concentration curve measured *in vivo* (AUC) ranging from 10000 ng.h/ml to 16250 ng.h/ml and preferably of about 12500 ng.h/ml.

25. **(Currently Amended)** A tablet according to claim 23 or 24, which wherein a pharmacokinetic profile is established from two tablets, each dosed at 500 mg, which is characterized by a maximum plasma concentration value ( $C_{max}$ ) ranging from 1600 ng/ml to 2600 ng/ml and preferably of about 2000 ng/ml.

26. **(Currently Amended)** A tablet according to any one of claims claim 23 or 24, which wherein a pharmacokinetic profile is established from two tablets, each dosed at 500 mg, which is characterized by a  $T_{max}$  value ranging from 2h and 3.25h and preferably of about 2.5h.

27. **(Cancelled)**

28. **(Currently Amended)** A tablet according to claim 23, wherein the tablet comprises dosed at 500 mg of metformin hydrochloride, releasing and releases between 50% and 100% of the active ingredient metformin hydrochloride dose and preferably at least 80% of the metformine chlorhydrate dose in 5 minutes in a physiological buffer medium at pH [[6,8]] 6.8 at 37°C.

29. **(Currently Amended)** A method for preparing a hydrodispersible non film-coated pharmaceutical tablet, characterized in that it comprises the following steps of comprising:

a) preparing (i) an internal core comprising a dispersible [[and]] or orodispersible solid pharmaceutical composition having the form of particles with a size lower than 710  $\mu\text{m}$ , containing [[the]] a metformin active ingredient, the composition comprising:

1) from 65% to 90% [[in]] by weight of the metformin active ingredient, optionally under provided in the form of a salt, or a combination of the metformin active ingredient with a hypoglycemic active ingredient;

2) from 0.5 to 4% [[in]] by weight of a binding agent or a combination of binding agents;

3) from 1% to 12% [[in]] by weight of a disintegrating agent or a combination of disintegrating agents;

4) from 0% to 10% [[in]] by weight of a diluting agent or a combination of diluting agents; and

5) one or more additional excipients,

through wet granulation of a mixture of metformin appropriate amounts, optionally under provided in the form of a salt or a combination of the metformin active ingredient with a hypoglycemic active ingredient, and a binding agent;

- b) drying the granules obtained in step a);
- c) adding to the granules obtained in step b) the mixture of excipients forming ii) an external layer comprising from 0.05% to 3% [[in]] by weight of a sweetening agent or a combination of sweetening agents; the weight percentages being expressed based on the total weight of said composition; and
- d) performing a compression of the granules obtained in step c).

30. **(Currently Amended)** A method for preparing a hydrodispersible non film-coated pharmaceutical tablet, ~~characterized in that it comprises the following steps of comprising:~~

a) preparing (i) an internal core comprising a dispersible [[and]] or orodispersible solid pharmaceutical composition having the form of particles with a size lower than 710  $\mu\text{m}$ , containing [[the]] a metformin active ingredient, the composition comprising:

1) from 65% to 90% [[in]] by weight of the metformin active ingredient, optionally under provided in the form of a salt, or a combination of the metformin active ingredient with a hypoglycemic active ingredient;

2) from 0.5 to 4% [[in]] by weight of a binding agent or a combination of binding agents;

3) from 1% to 12% [[in]] by weight of a disintegrating agent or a combination of disintegrating agents;

4) from 0% to 10% [[in]] by weight of a diluting agent or a combination of diluting agents; and

5) one or more additional excipients,

through dry granulation of a mixture of metformin appropriate amounts, optionally under provided in the form of a salt or a combination of the metformin active ingredient with a hypoglycemic active ingredient, and a binding agent;

b) compacting the dry granules obtained in step a);

c) adding to the granules obtained in step b) the mixture of excipients forming (ii) an external layer comprising from 0.05% to 3% [[in]] by weight of a sweetening agent or a combination of sweetening agents; the weight percentages being expressed based on the total weight of said composition; and

d) performing a compression of the granules obtained in step c).

31. **(Currently Amended)** A method for preparing a hydrodispersible non film-coated pharmaceutical tablet, characterized in that it comprises the following steps of comprising:

a) preparing a mixture of (i) an internal core comprising a dispersible [[and]] or orodispersible solid pharmaceutical composition having the form of particles with a size lower than 710  $\mu\text{m}$ , containing [[the]] a metformin active ingredient, the composition comprising:

- 1) from 65% to 90% [[in]] by weight of the metformin active ingredient, optionally under provided in the form of a salt, or a combination of the metformin active ingredient with a hypoglycemic active ingredient;
- 2) from 0.5 to 4% [[in]] by weight of a binding agent or a combination of binding agents;
- 3) from 1% to 12% [[in]] by weight of a disintegrating agent or a combination of disintegrating agents;
- 4) from 0% to 10% [[in]] by weight of a diluting agent or a combination of diluting agents; and
- 5) one or more additional excipients, through dry granulation of a mixture of the metformin appropriate amounts, optionally under provided in the form of a salt or a combination of the metformin active ingredient with a hypoglycaemic active ingredient, and the binding agent;
  - b) adding to the granules obtained in step a) the excipient mixture forming (ii) an external layer comprising from 0.05% to 3% [[in]] by weight of a sweetening agent or a combination of sweetening agents; the weight percentages being expressed based on the total weight of said composition; and
  - c) performing a compression of the granules obtained in step b).